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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,832	09/19/2005	Jay M. Edelberg	955-39 PCT-US	9990

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,832	EDELBERG ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,18,33,52,66,75,86,102,116,127,139,147,157 and 162-165* is/are pending in the application.

4a) Of the above claim(s) *1,18,33,52,66,75,86,102,116,139,147 and 157* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *127 and 162-165* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/15/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response is acknowledged.

As noted previously, Applicant diligently points out the suggestions for potential support in the specification, that the Examiner provided Applicant in researching ways to address the 112 2nd paragraph rejection. Though one of Applicant's amendments (term "condition") has raised a new 112 2nd, as this is a result of Applicant's efforts in view of the Examiners suggestions, the Examiner is making the modified new grounds of rejection under 112 2nd Non-Final. Applicant is welcomed to telephone the Examiner should any questions as to amendment options hereafter arise.

Election/Restrictions

As stated previously, Applicant's election without traverse of Group I, claims 92, 127 and 158-165, as drawn to the elected peptide of the invention of SEQ ID NO: 4 - AARGQAV, in the reply filed on 5/9/08, is acknowledged.

Claim Rejections - 35 USC § 112 2nd-Maintained, Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 127 and 162-165 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained. Applicant's amendment and response are acknowledged, but not found persuasive.

In an interview with Applicant, the Examiner indicated the 35 USC 112 2nd rejection would be maintained as claim 127 has not been amended to recite the suggested language that only trkB receptors were found to be bound, as opposed to any merely 'preferentially' and that any heart microvasculature can still be bound. The claim remains indefinite as only trkB receptors were found to be bound in the description. Appropriate amendment is still required, absent evidence to the contrary.

Additionally, a proposed claim amendment to or in line with the following was suggested:

> 127. (Currently Amended) A method for delivering a functional moiety to a trkB receptor in the heart microvasculature in a mammal, the method comprising administering a conjugate, said conjugate comprising a peptide comprising the amino acid sequence of SEQ ID NO: 4 and said functional moiety.

In claim 127 (and dependent claims 158-165) the amended phrase and thus claims are indefinite based on, as stated before "the description only describes that SEQ ID NO: 4 is known to bind a single BDNF receptor: trktB and not any BDNF receptor; and only in the microvasculature, and not the broader vasculature. [IT IS SUGGESTED APPLICANT CONSIDER DISTINCTLY CLAIMING THE INVENTION TO BINDING trktB RECEPTOR AND MICROVASCULATURE]. trktB receptors were found to be more prevalent in older age individual's hearts, than younger age hearts."

If amended, Applicant has amended the invention to be drawn to a method of delivering a function moiety attached to SEQ ID NO: 4 to a trkB receptor, which was not found in the prior art of record. An updated search of the art will be conducted if positively amended thereto, in response to this Office Action.

The remainder of the previous rejection stated:

However, the description does not make the 'connection/nexus' that trktB receptors in the older art (v. fewer or none in the younger art) equate to ANY heart with trktB receptors as being "damaged". Namely, there is not a link between this specific receptor and what disorder/pathology it causes. Thus, it is unclear how the claimed invention can even determine a DAMAGED heart, let alone whether a heart is "healthy". The terms have not been quantified in such a way that any one using the invention would know that such a heart is damaged, or not damaged BUT MAY STILL BE, simply because binding of SEQ ID NO: 4 has been evidenced - thereby indicating that trktB receptors are present. As such, the metes and bounds of the invention, read in light of the description, only appear to indicate the latter - whether a/more than1 trktB receptor is present or not. As to what if any DAMAGE the presence of this receptor can be correlated to, this is unclear and thus the claimed invention is indefinite as claimed, based on the lack of quantified definition of what equals a "healthy heart" and what equals a "damaged heart". A heart can still have "damage" however small, and be deemed otherwise "healthy" to one practitioner OR NOT to another. Or have a slight, completely unrelated factor to trktB and be deemed "damaged" - yet SEQ ID NO: 4 would have not binding thereof, if no trktB receptors were present - and thus, based on this method, the heart would be falsely determined as "healthy".

Sequence Rules-New

As stated in the Interview Summary of 5/7/10, the Examiner telephoned to indicate that sequences of 4 or > amino acids had been discovered in the application that did not have a SEQ ID NO: sequence identifier in the specification or that corresponded thereto in the sequence listing of record. Applicant was put on notice that a new sequence listing, statement, and amendment needed to be filed to address this.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. 37 CFR 1.821(a) presents a definition for "nucleotide and/or amino acid sequences." **SPECIFICIALLY, the instant application (and at least 13 other applications in this family) contains an unbranched specifically defined sequence of more than four amino acids, in the specification, without a sequence identifier SEQ ID NO:.** Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. "Specifically defined" means those amino acids other than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2 (see MPEP § 2422).

Since the present sequence compliance request is being sent along with the Office Action on the merits (in the interests of compact prosecution, and since no sequences are expressly claimed), Applicant is given THREE MONTHS (instead of the normal ONE MONTH, or THIRTY DAYS, whichever is longer), from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Appropriate correction is required.

Elected Invention Free of the Art

SEQ ID NO: 4 was not found to be reasonably taught or suggested by the prior art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 5/8/10

/Maury Audet/
Examiner, Art Unit 1654